

**REMARKS****Status of the Application and Claims**

Claims 1-9, 12, 14-16, and 19-23 are under examination. Claims 1-9, 12, 14-16, and 19-23 have been canceled in the current amendment. New claims 24-38 have been added. Support for the claims can be found at least at page 4, line 6 and page 16, line 21. No new matter has been added by way of this amendment.

**Withdrawn Rejections**

Applicants acknowledge the Office's withdrawal of the following rejections:

the rejection of claim 3 under 35 U.S.C. § 112, second paragraph;

the rejection of claims 1-3, 5-7, 9-10, 12, 14-16, and 19-23 under 35 U.S.C. § 103(a) as being unpatentable over Jehanli et al., (1996) and Cole et al., (US Patent 4,859,612);

the rejection of claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Jehanli et al. (1996) and Cole et al., (US Patent 4,859,612) as applied to claims 1, and further in view of de Jaeger et al., (US Patent 4,837,168); and

the rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Jehanli et al., and Cole et al., further in view of Baker et al.

*See* Office Action, 7/22/2005, pp. 2-3.

**35 U.S.C. § 102**

Claims 1-4, 6, 7, 9, 12, 14-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by de Jaeger et al. (US Patent 4,837,168). *Id.*, p. 3. Claims 1-4, 6, 7, 9, 12, 14-15 have been canceled

by the current amendment. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102, second paragraph, be withdrawn as moot.

**35 U.S.C. § 103(a) Rejection Based on Jehanli et al. and Cole et al. in view of Maggio**

The Office rejected claims 1-3, 5-7, 9, 12, 14-16, and 19-21 under 35 U.S.C. § 103 (a) based on Jehanli et al. (1996) and Cole et al. (US Patent 4,859,612) in view of Maggio (1987). *Id.*, p. 6.

According to the Office, it would have been “prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., wherein no more than routine skill would have been required to incorporate the gold labeled antibody of Cole et al., and use a stick instead of a well as the solid phase carrier as taught by Maggio et al.” *Id.*, p. 8. The Applicants’ believe this rejection is moot since claims 1-3, 5-7, 9, 12, 14-16, and 19-21 have been canceled. To the extent this rejection is not deemed moot, however, Applicants believe the rejection is overcome for the reasons provided herein and respectfully traverse.

The Federal Circuit has held that there must be a clear and particular suggestion in the prior art to combine the teachings of the cited references in the manner proposed by the Examiner. As explained by the Federal Circuit, “[o]ur case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.” *In re Dembiczak* 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999).

The Examiner can meet the burden of establishing a prima facie case of obviousness “only by showing some objective teaching in the prior art or that knowledge generally available to one of

ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” *In re Fine*, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988) (internal citations omitted) (emphasis added).

On January 18, 2002, the Federal Circuit again reaffirmed the Examiner’s high burden to establish a *prima facie* case of obviousness and emphasized the requirement for specificity. In *In re Sang-Su Lee*, the Federal Circuit held that “[t]he factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.” 277 F.3d 1338, 1433 (Fed. Cir. 2002)(emphasis added). Further, the Federal Circuit explained that

[t]he need for specificity pervades this authority... the examiner can satisfy the burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *Id.* (internal citations and quotation omitted) (emphasis added).

In the present case, Applicants respectfully submit that the requisite objective teaching is not present in the references—notwithstanding the Examiner’s comments on pages 11-14 of the Office Action dated July 22, 2005. *See* Office Action, 7/22/2005, pp. 11-14. In fact, since Jehanli et al. teach a system where a free drug competes with drug-conjugate coated onto a microtitre well to bind to drug-specific antibodies and Cole et al. describe a sandwich mode system in which the to-be-detected drug reacts with both antibody associated with solid phase particles and antibody associated with metal particles, they teach away from the combination suggested by the Examiner. Maggio’s alleged teaching cannot cure this objective teaching. Withdrawal of the rejection is respectfully requested.

Furthermore, the asserted prior does not disclose the determination of the drug within 5 to 30 minutes. To support its position, the Office reminds the Applicants that the claims are drawn to a kit and as such, a recitation of the intended use, such as a determination of the drug within 5 to 30 minutes, must result in a structural difference between the claimed invention from the prior art. *Id.*, pp. 13-14. Regardless of the merit of the argument, the present claims of this amendment are drawn to a method of determining the presence of a drug from a sample within 5 to 30 minutes and the rejection is traversed.

Additionally, the Applicant respectfully notes that both Jehanli et al. and Cole et al. disclose total detection development times beyond the time disclosed in the present invention. *See* Jehanli et al., p. 915, right column, lines 6-12; Cole et al., col. 9 to col. 19. The Applicants respectfully request the rejection be withdrawn.

The Office relies on Maggio to cure the absence of the “stick” disclosure in Jehanli et al. and Cole et al. *See* Office Action, 7/22/2005, p. 8 (stating that neither Jehanli et al., nor Cole et al., teach using a stick as the first part instead of a well). The Office states that Maggio teaches that the solid phase carrier “can be preformed into discs, tubes, sticks, microplates or the like (page 186).” *Id.* (Emphasis added). But this is incorrect. Maggio specifically discloses that “[t]he solid phase can be in the form of particles of cellulose, polyacrylamide or agarose, or the solid-phase carrier can be preformed into discs, tubes, beads, or microplates.” Maggio, p. 186. Remarkably absent from the disclosure is of course “sticks.” Maggio goes on to distinguish his teaching from previous researchers and states that “[e]arlier manufacturers were more concerned with the shape of the bead, plate, tube or microplate . . . .” *Id.*, p. 187. Again, there is no mention of a stick and it is thus unclear to the Applicant that the reference was cited for the proposition. Nevertheless, because

neither Jehanli et al., Cole et al., or the combination of the two references, nor Maggio teach or suggest the claimed invention, a *prima facie* case of obviousness can not be established.

Applicants respectfully assert that the Office failed to establish a *prima facie* case of obviousness for at least the reasons stated above. Accordingly, Applicants further respectfully request the above rejections be withdrawn.

**35 U.S.C. § 103(a) Rejection Based on de Jaeger et al. and Jehanli et al. in view of Baker et al.**

The Office rejected claims 8 and 22-23 under 35 U.S.C. § 103(a) as being unpatentable over de Jaeger et al. (US Patent 4,837,168) and Jehanli et al. (1996) as applied to claims 1-2 and 6-7 above, further in view of Baker et al., (US Patent 5,624,806). *Id.*, p. 9. Applicants respectfully request that the rejection is moot for canceled claims 8 and 22-23, but is otherwise traversed in light of the deficiencies noted in the references for the *prima facie* case of obviousness above and below.

Specifically, de Jaeger et al. disclose a method for determining a component of a complex formed between at least one specific binding protein and its corresponding bindable substance that comprises at least one component of said complex with a marker consisting of colorable latex particles. *Id.*, pp. 3-4. As such, unlike the Applicants' invention, the component to be determined is a component of a complex formed between a binding protein and a bindable substance. In the present invention, the detection of a drug is conducted by means of a competition between the drug in the biological fluid and the drug conjugate immobilized on the first part. Furthermore, while de Jaeger et al. disclose the colorable latex particles (*id.*, p. 4), it does not disclose the use of particles as disclosed by the Applicants' invention.

Applicants respectfully assert that the Office failed to establish a *prima facie* case of obviousness for at least the reasons stated above. Baker et al., even if it were to teach the antigen

lisinopril and antibodies to lisinopril, as stated by the Office (*id.*, p. 10), it could not cure failure to establish the *prima facie* case of obviousness. Accordingly, Applicants further respectfully request the above rejections be withdrawn.

In view of the foregoing remarks, Applicants request the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By: 

M. Andrew Holtman  
Reg. No. 53,032